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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/581,890 | 08/28/2000 | Oliver Brustle | V0S-012 | 7106 |

7590 06/05/2002

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EXAMINER

BAKER, ANNE MARIE

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 06/05/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/581,890

Applicant(s)

BRUSTLE, OLIVER

Examiner

Anne Baker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 and 39-46 is/are pending in the application.
- 4a) Of the above claim(s) 16-30 and 39-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☒ Other: *detailed action*.

DETAILED ACTION

The response filed March 8, 2002 (Paper No. 10) has been entered.

Applicant's election, with traverse, of Group I, Claims 1-15 and 46 in Paper No. 10 is acknowledged. The elected invention is drawn to isolated embryonic stem cell-derived precursor cells with neuronal and glial properties and a pharmaceutical composition comprising said precursor cells.

The traversal is on the grounds that the cells of Group I cannot be made by any method other than the method of Group III. This is not found persuasive because the cells of Group I, as claimed, are disclosed in the prior art and were not made by the method of Group III. Thus, the method of Group III is not specially adapted to making the cells of Group I, and therefore unity of invention does not exist as asserted by Applicants. Applicants also argue that the neural spheres are aggregates of the neuronal precursor cells of Group I. However, this is incorrect. The argument is not found persuasive because the claims specifically recite that the cells in the neural spheres are "neural cells **differentiated** from precursor cells according to claim 1." Thus, the cells in the neural spheres of Group II are differentiated cells, whereas the cells of Group I are precursor cells. These are distinct cell types.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-30 and 39-46 are pending in the instant application.

Claims 1-15 and 46 are examined herein.

Claims 16-30 and 39-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-15 and 46 are indefinite in their recitation of “neuronal and glial properties” because it is unclear what specific properties the claimed cells are required to have. The metes and bounds are not clearly set forth.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-15 and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 5,851,832 (Weiss et al., 1998).

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Weiss et al. (1998) disclose mammalian neural stem cells. These cells can be derived from embryonic, juvenile, or adult mammalian neural tissue. The cells can be induced to differentiate into neurons, astrocytes, and oligodendrocytes. Although the instantly claimed cells are limited to cells derived from embryonic stem cells, no particular identifying characteristics are recited in the claims other than the requirement that the cells have "neuronal and glial properties." The cells disclosed by Weiss et al. satisfy this limitation. Weiss et al. further disclose that the neural stem cells form neurospheres in suspension culture (Column 17, lines 16-26). The specification particularly states that "[i]n the continued presence of a proliferation-inducing growth factor such as EGF or the like, precursor cells within the neurosphere continue to divide resulting in an increase in the size of the neurosphere and the number of undifferentiated cells."

Claims 1-15 and 46 are product-by-process claims. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. The patentability of a product does not depend on its method of production. See M.P.E.P. 2113. Thus, the claims read on neural stem cells disclosed in the prior art, for the reasons set forth herein below.

In the absence of evidence to the contrary, the neural stem cells disclosed and claimed (Claims 55-80) by Weiss et al. are indistinct from those instantly claimed.

Thus, the claimed compositions are disclosed in the prior art.

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Conclusion


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Baker whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Anne-Marie Baker, Ph.D.


ANNE-MARIE BAKER
PATENT EXAMINER